



Verrica Pharmaceuticals Licenses LTX-315, A First-in-Class Oncolytic Peptide Based Immunotherapy, from Lytix Biopharma AS, for the Treatment of Dermatologic Oncology Indications

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WEST CHESTER, Pa., Aug. 11, 2020 (GLOBE NEWSWIRE) -- Verrica Pharmaceuticals Inc. ("Verrica") (NASDAQ: VRCA), a dermatology therapeutics company developing medications for skin diseases requiring medical interventions, today announced that the Company has entered into an exclusive worldwide license agreement with Lytix Biopharma AS ("Lytix") to develop and commercialize LTX-315 for dermatologic oncology indications. Verrica intends to focus initially on basal cell and squamous cell carcinomas as the lead indications for development. LTX-315 is a first-in-class oncolytic peptide that is injected directly into a tumor to induce immunogenic cell death. The compound has demonstrated positive tumor-specific immune cell responses in multi-indication Phase I/II oncology trials.

"This is an important milestone in the broadening of Verrica's strategy to bring breakthrough treatments for skin diseases to patients and physicians, as dermatologic cancers are highly prevalent and many patients suffer from them," said Dr. Gary Goldenberg, Verrica's Chief Medical Officer. "Innovation in dermatology is one of the primary drivers that prompted me to recently join Verrica, and LTX-315's unique mechanism of action is clearly an innovative approach to potentially provide significant improvement over invasive surgery. LTX-315 has the potential to revolutionize one of the most common disease states in dermatology – non-melanoma skin cancers. We look forward to leveraging Verrica's depth of clinical development experience to develop this innovative asset for the potential benefit of patients. We intend to submit an IND in the United States for LTX-315 during the first half of 2021 and commence clinical development thereafter."

"Skin cancer is the most common cancer in the U.S., with 5 million diagnoses of basal and squamous cell carcinomas each year,"¹ said Darrell Rigel, MD, Clinical Professor of Dermatology at NYU. "Patients are typically treated with surgery, which can result in damage to healthy tissue, pain, and permanent scarring. LTX-315 is a clinical-stage, non-surgical immunotherapy product candidate that directly targets cancerous skin cells, with the potential to transform the treatment of skin cancer by offering a therapeutic alternative to surgery."

"We are pleased to enter into this collaboration with Verrica, which has significant expertise within the field of dermatology," said Øystein Rekdal, Lytix's CEO. "Our lead drug candidate, LTX-315, has shown very promising efficacy and safety signals in cancer patients during Phase I/II studies and we are excited that this partnership with Verrica will expand the applications for LTX-315."

Under the terms of the agreement, Lytix will be entitled to receive an upfront payment, contingent regulatory milestones based on achievement of specified development goals, and sales milestones, with aggregate payments of up to \$113.5 million, in addition to tiered royalties based on worldwide annual sales. The agreed upon royalty rates start in the low double digits and increase to the mid-teens based on net sales achieved.

Verrica is solely responsible for the development, regulatory filings, and commercialization of LTX-315 in dermatology, while Lytix is responsible for manufacturing the active pharmaceutical ingredient. The license includes worldwide rights for Verrica to develop and commercialize LTX-315 for all malignant and pre-malignant dermatological indications, except for metastatic melanoma and metastatic Merkel cell carcinoma.

The Company reaffirms its belief that its existing cash, cash equivalents, and marketable securities will be sufficient to support planned operations, inclusive of this agreement with Lytix and LTX-315 development activities, at least through the fourth quarter of 2021.

About Verrica Pharmaceuticals Inc.

Verrica is a dermatology therapeutics company developing medications for skin diseases requiring medical interventions. The Company's late-stage product candidate, VP-102, is a potential first-in-class topical therapy for the treatment of molluscum contagiosum. Verrica submitted an NDA for VP-102 for the treatment of molluscum in September 2019. A Complete Response Letter was received from the FDA regarding the NDA for VP-102 on July 13, 2020. If approved, VP-102 will be marketed in the United States under the conditionally accepted brand name YCANTH™. In addition, Verrica has successfully completed a Phase 2 study of VP-102 for the treatment of common warts and is currently conducting a Phase 2 study of VP-102 for the treatment of external genital warts. The Company is also developing VP-103, its second cantharidin-based product candidate, for the treatment of plantar warts. For more information, visit www.verrica.com.

About Lytix Biopharma AS.

Lytix is a Norwegian clinical stage immuno-oncology company with a broadly patented oncolytic molecule platform. Lytix Biopharma's lead compound, LTX-315, is administered intra-tumorally and works by a unique mechanism of action via immunogenic cell death, which results in an effective release of tumor antigens and potent immunostimulatory molecules. Phase I/II studies have demonstrated an increase in CD8+ TILs in the majority of evaluated patients resulting in size reduction of treated and distant non-treated lesions. For more information, visit www.lytixbiopharma.com.

Forward-Looking Statement

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “believe,” “expect,” “may,” “plan,” “potential,” “will,” and similar expressions, and are based on Verrica’s current beliefs and expectations. These forward-looking statements include expectations regarding the potential clinical development and benefits of LTX-315, including the timing of the IND submission, the potential benefits and potential approval and commercialization of YCANTH™ for the treatment of molluscum, the Company’s expectations with regard to its interactions and communications with the FDA, including its expectation to discuss with the FDA regarding the issues raised in the CRL and the Company’s plans to address them, the clinical development of product candidates for additional indications, including common warts, external genital warts and plantar warts, and the Company’s expectations with respect to its cash reach. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the drug development process and the regulatory approval process, Verrica’s reliance on third parties over which it may not always have full control, uncertainties related to the COVID-19 pandemic and other risks and uncertainties that are described in Verrica’s Annual Report on Form 10-K for the year ended December 31, 2019, Verrica’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, and other filings Verrica makes with the U.S. Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and are based on information available to Verrica as of the date of this release, and Verrica assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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¹ <https://www.cancer.org/cancer/basal-and-squamous-cell-skin-cancer/about/key-statistics.html>



Source: Verrica Pharmaceuticals Inc.